UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/037,657	03/10/98	WILLSON T	10857Z

HM22/0516

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EXAMINER	
HAMUD,F	
ART UNIT	**PAPER NUMBER**
1646	13

DATE MAILED: 05/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

File copy

Office Action Summary	Application No. 09/037,657	Applicant WILLSON et al.
	Examiner Fozia Hamud	Group Art Unit 1646

☒ Responsive to communication(s) filed on *Apr 4, 2000*.

This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-34* is/are pending in the application.

Of the above, claim(s) *1-19, 28, 29, and 31-34* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *20-27 and 30* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) *08/928,720*.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The request filed on 04/04/2000 in Paper No.12, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/037,657 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restriction

2. Applicant elected with traverse, claims 20-27 and 30 in Paper No. 7 filed on June 24, 1999. Therefore, claims 1-19, 28-29, and 31-34 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

The restriction requirement is still deemed proper and is therefore made FINAL, see the previous office action, mailed on 10/4/99 in Paper No:10, page 3.

Specification

The following objections to the specification is maintained for reasons of record set forth in the previous office action, mailed on 10/4/99 in Paper No:10, pages 4-5.

3a. Acknowledgment is made of applicant's claim for foreign priority based on the following applications filed in Australia: PN 6135 filed on October 23, 1995; PN 7276 filed December 22, 1995 and PO 2208 filed on September 9, 1996. It is noted, however, that applicants have not filed certified copies of the Australian applications as required by 35 U.S.C. 119(b). Until the certified copies of the Australian patents are submitted, art rejections dated after the foreign priority will still be applied.

3b. The Brief Description of the Drawing should be corrected. Figure 1 is shown in two panels (Figure 1A and Figure 1B), however, the Brief Description of the drawing only reflects one figure.

Appropriate correction of the Brief Description of the Drawing which reflects Figure 1A and Figure 1B is required.

3c. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
© Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(I) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

On pages 29-28 of the instant specification there are descriptions for the figures with the title "In the Figures", however, this should be titled "Brief Description of the Figures" and should be placed between the summary of the invention and the detailed description of the invention. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

4. The rejection of claims 20-27 and 30 under 35 U.S.C. 112, first paragraph is maintained for reasons of record set forth on page 5-10 of the office action mailed on 10/4/99, in Paper No:10.

5a. The rejection of claims 20-27 and 30 under 35 U.S.C. 112, second paragraph is maintained for reasons of record set forth on page 10-12 (4a-4e)of the office action mailed on 10/4/99, in Paper No:10.

5b. The rejections of claim 30 under 35 U.S.C. 112, second paragraph, for reciting "having" and for reciting "%identity" is withdrawn.

6a. The rejection of claim 20 under 35 U.S.C *§ 102*(b) as being anticipated by D'andrea et al (August/1990), is maintained for reasons of record set forth on page 12-13 of the office action mailed on 10/4/99, in Paper No:10.

6b. The rejection of claim 30 under 35 U.S.C *§ 102*(b) as being anticipated by Marra et al (June/1996), is maintained for reasons of record set forth on page 13-14 of the office action mailed on 10/4/99, in Paper No:10.

New rejections and issues

Claim Rejections - 35 U.S.C. § 101/112

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7a. Claims 20-24 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Instant claims are directed to an isolated hemopoietin receptor comprising the amino acid sequence set forth in SEQ NO:13, 15, 17, 19, 25 or 29. The specification describes the polypeptides of SEQ ID NO:13, 15, 17, 19, 25 or 29, as being a novel hemopoietin receptor, (page 3, lines 11-14).

However, the instant specification does not disclose any information regarding which hemopoietin does this receptor bind to, or any functional characteristics of the claimed hemopoietin receptor. The instant specification discloses that the claimed hemopoietin receptor is expressed in salivary gland, Lung and testis of the adult mouse, and that it is expressed in fetal tissues from day 10 of gestation through birth, however, it does not show the significance of this expression and why it is an important receptor. The specification also discloses a knockout mouse and shows lack of this receptor is lethal during embryonic development or immediately after birth, (page 57, lines 5-10). However, the specification does not disclose any phenotype for the mice that lack this receptor, although it is apparent that this receptor is important, it is not clear why or what biological processes it is involved in. One asserted utility for the claimed hemopoietin receptor is the generation of a range of therapeutic molecules capable of modulating the expression of the receptor, such as agonists and antagonists, (page 15, lines 14-20). However, since it is not known what pathological conditions that this receptor is involved in and whether is up-regulated or down-regulated in these pathological processes, the skilled artisan would not know how to modulate it. While, the instant specification discloses conventional protein administration techniques, it does not disclose which disease or diseases could the claimed receptor be used to treat, neither does it disclose any working examples demonstrating that the claimed receptor was indeed used to treat any disease. The specification establishes no connection between any pathological condition and the claimed receptor, i.e, is the claimed receptor over expressed, under expressed or completely lacking in these diseases? Neither does it show the mechanism of action of said receptor. The specification provides no working examples as to the activity of the claimed protein, and one of ordinary skill in the art would not be

able to predict what activity would be possessed by the protein of the instant application based solely because it may be a member of hemopoietin receptor family. Therefore, without knowing the specific cytokine that binds to said receptor, or its' biological function, neither a substantial utility nor a specific utility can be established for it. The fact that the claimed polypeptide might belong to the hemopoietin receptor family is not enough to establish a substantial utility or a specific utility for it.

7b. Claims 20-27 and 30 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. There is no biological activity disclosed for the claimed hemopoietin receptor, and the specific cytokine the binds to it has not been disclosed, therefore, there is no specific or substantial utility for the claimed polypeptide, thus the skilled artisan would not know how to use the polypeptide of SEQ NO:13, 15, 17, 19, 25 or 29.

Conclusion

8. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud

Art Unit: 1646

Patent Examiner
Art Unit 1646
May 10, 2000

PREMA MERTZ
PRIMARY EXAMINER